

Appln. No.: 10/091,172
Reply Brief Dated: February 9, 2009

BSI-559US (formerly ENDOV-55674)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/091,172
Appellant: Juan I. Perez et al.
Filed: March 4, 2002
Title: STAGED ENDOVASCULAR GRAFT DELIVERY SYSTEM
T.C./A.U.: 3774
Examiner: Ann M Schillinger
Confirmation No.: 9937
Docket No.: BSI-559US (formerly ENDOV-55674)

REPLY BRIEF UNDER 37 C.F.R. § 41.37

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SIR :

Appellants submit this Reply Brief in response to the Examiner's Answer mailed on December 9, 2008. The arguments set forth herein address issues raised in the Examiner's Answer and supplement the arguments set forth in the Second Supplemental Appeal Brief filed on September 10, 2008.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within two months from the date of mailing of the Examiner's Answer.

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I. STATUS OF CLAIMS

Upon entry of the Amendment Under 37 C.F.R. 41.33 submitted with the Appeal Brief, claims 1-25 are pending. Claims 10, 11 and 23 were objected to, however, claims 10, 11 and 23 have been amended into independent form. Claims 10, 11 and 23 should now be in condition for allowance. Claims 1-9, 12-22, 24 and 25 stand rejected. Claims 1-9, 12-22, 24 and 25 are the subject of this appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal is whether claims 1-9, 12-22, 24 and 25 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. in view of Staehle et al.

III. ARGUMENT

Rejection Under 35 U.S.C. §103(a) Over U.S. Patent No. 6,090,136 in View of U.S. Patent No. 6,132,458

The Examiner's Answer indicates that the Reply Brief did not include sufficient evidence in support of the argument that the references are inoperable, however, the Reply Brief overlooks that the initial burden of proof is on the USPTO to establish a *prima facie* case of obviousness. As explained in the Appeal Brief, to "establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Second, there must be a reasonable expectation of success. Additionally, as set forth by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Appellants respectfully submit that the Examiner has failed to provide any basis for there to be a reasonable expectation of success other than the unsupported statement on page 4 of the Reply Brief that "there is a reasonable expectation of success that the structure of McDonald et al. will not become stuck in the funnel structure of the Staehle et al. device."

As explained beginning at column 7, line 23 of McDonald et al. "the perforated sheet 11 is rolled up into a tubular stent 13 such as by rolling the sheet 11 around a mandril (not illustrated). The rolled tubular body 13 is then loaded into the distal end 102 of the introduction catheter 104, either at a point of manufacture, or at the clinical site. The radially outwardly directed bias of the tubular body 13, as discussed in greater detail infra, causes the tubular body 13 to press radially outwardly against the interior wall of the catheter 104, thereby retaining the tubular body 13 in position within the catheter 104." (emphasis added). Positioning of the tubular stent 13 of McDonald et al. in the receiving opening 17 in the device 10 of Staehle et al. would cause the stent 13 to unroll. There is no basis for one to believe the funnel 19 of the device 10 will cause the unrolled stent 13 to reroll. Appellants respectfully

submit that the Examiner has failed to provide a basis to support a reasonable expectation of success of the combined device.

Furthermore, even if the combination was proper, the combined references still fail to teach each limitation of the claimed invention. Independent claim 1 recites in part "a loading capsule configured to receive a subsequent treatment component. . ." The Reply Brief indicates that because the pusher 20 of Stahle et al. is removable, the device 10 is configured to receive a subsequent treatment component. Such a position overlooks the teachings of Staehle et al. which only contemplates a single stent which is preloaded and sealed in the constricting sheath and there is no teaching or suggestion in either reference of a capsule configured to receive a subsequent treatment component. The cited references, alone or in any reasonable combination, fail to teach each element of the claimed invention.

Independent claim 18 recites in part "a pusher assembly configured to releasably receive each of the plurality of endovascular graft components; a loading capsule assembly configured to receive the pusher assembly and including a superior terminal end; . ." Neither of the cited references teaches or suggests a pusher configured to releasably receive each of the plurality of endovascular graft components and to be received in a loading capsule assembly. The Reply Brief indicates that the claim does not specify that the pusher assembly acts on one component at a time and that by acting on the multi-component graft assembly as a whole, the limitation is met. However, claim 18 recites that the pusher assembly releasably receives each of the plurality of the endovascular graft components. The pusher 134 of McDonald et al. pushing on a continuous chain of stents 184, as shown in Fig. 12 thereof, would not be receiving each of those graft components. The cited references, alone or in any reasonable combination, fail to teach each element of the claimed invention.

Independent claim 22 recites in pertinent part "inserting initial introducer sheath loaded with the endovascular graft component within vasculature and positioning a superior end of the initial introducer sheath at the repair site; retracting the initial introducer sheath to deploy the endovascular graft component; mating the superior terminal end of the loading capsule with the inferior end of the initial

introducer sheath; . . ." With respect thereto, the Reply Brief indicates that the claimed invention does not require an order of steps and that the preloading of multiple stents as taught by McDonald et al. meets the claimed limitations. The Examiner overlooks that the claim recites mating of the loading capsule with the inferior end of the introducer sheath. There is no teaching or suggestion that such step would be included in the preloaded stent as suggested by the examiner. The cited references, alone or in any reasonable combination, fail to teach each element of the claimed invention.

Accordingly, for at least the reasons set forth above and in Appellants' Second Supplemental Appeal Brief filed on September 10, 2008, Appellants respectfully contend that each of the claims of this application are now in condition for allowance. Accordingly, appellants respectfully request reversal of the January 12, 2007 Rejection.

Respectfully submitted,



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